K132060

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510(k) SUMMARY
DuraBlue™ Sterilization Wrap

Manufacturer:	Cardinal Health 200, LLC 1430 Waukegan Road Waukegan, IL 60085
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Date summary Prepared:	November 15, 2013
Trade Name:	DuraBlue™ Sterilization Wrap
Classification:	Class II per 21 CFR § 880.6850
Classification Name:	Sterilization Wrap
Common Name:	Sterilization Wrap
Product Code:	FRG
Predicate Device:	K123857 – DuraBlue™ Sterilization Wrap – Johnson & Johnson STERRAD® NX and STERRAD® 100NX K123289 - DuraBlue™ Sterilization Wrap – Pre-Vacuum Steam (4 min/270°F) & 100% Ethylene Oxide (EO) K120658 – DuraBlue™ Sterilization Wrap – STERRAD® 100S and Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus, and Amsco® V-PRO® MAX Low Temperature Sterilization Systems

Description:

DuraBlue™ Sterilization Wraps are made from 100% polypropylene spunbond-meltblown-spunbond (SMS) trilaminate nonwoven fabric. Each double-layer wrap is comprised of a single sheet of SMS fabric that has been folded in half and sealed to itself on the three non-folded edges. This wrap design allows for use of the simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically. This product is for over-the-counter use only.

They are intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S System
- Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles
- Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles
- Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus and Amsco® V-PRO® MAX Low Temperature Sterilization Systems

The modification to the predicate devices is the clarification to the sterility maintenance information provided in the Indications for Use portion of the Instructions for Use labeling and involves extending the real-time aging data from 180 days to 365 days. This change is being made in order to comply with 21CFR880.6850 which states "A sterilization wrap (pack, sterilization wrapper, bag, or accessories) is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device *until used*." Additionally, maintenance of package sterility was validated with real-time testing for a duration of 365 days for each indicated sterilization process.

Extensive performance testing has also been completed on DuraBlue™ Sterilization Wrap. Successful completion of the sterilization performance tests demonstrated that the wrap allows for sterilization of the enclosed contents and also maintains sterility of the enclosed devices. Physical properties testing included in this submission also supports the fact that the integrity of the wrap properties is not compromised after sterilization by the indicated sterilization processes and storage because the polypropylene material is inert and very stable.

This submission covers six different models of DuraBlue™ Sterilization Wrap. Each model is made from material of a different basis weight, though all models utilize the same material technology.

Indications for Use

DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S system.

- Advanced Sterilization Products (ASP) STERRAD® NX system, Standard and Advanced Cycles

- Advanced Sterilization Products (ASP) STERRAD® 100NX system, Standard, Flex, Express, and DUO Cycles

- Lumen, Non Lumen, and Flexible Cycles in the Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus and Amsco® V-PRO® maX Low Temperature Sterilization Systems

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.

For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600. Models CH400, CH500 and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.

For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55 °C. Models CH400, CH500 and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less.

All models of DuraBlue™ Sterilization Wrap have been validated for Advanced Sterilization Products (ASP) STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.

All models of DuraBlue™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX cycles in Table 1.

All models of DuraBlue™ Sterilization Wrap have been validated for use with the STERIS Amsco® V-PRO® cycles in Table 2. The DuraBlue™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS Amsco® V-PRO® sterilization cycles.

Table 1 – Validated Advanced Sterilization Products STERRAD® NX and STERRAD® 100NX Sterilization Cycles

Advanced Sterilization Products (ASP) STERRAD® System and Cycle	Maximum Recommended Chamber Load	Intended Load
ASP STERRAD® NX Standard Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens
ASP STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter
ASP STERRAD® 100NX Standard Cycle	21.4 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens (A maximum of five lumens per tray per sterilization cycle)
ASP STERRAD® 100NX Flex Cycle	12.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (A maximum of two flexible endoscopes, one per tray per sterilization cycle)
ASP STERRAD® 100NX Express Cycle	10.7 lbs	Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens
ASP STERRAD® 100NX Duo Cycle	13.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

Table 2 – Validated STERIS Amsco® V-PRO® cycles

Amsco® V-PRO® Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Table 3 - Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weight[2]			
		Pre-Vacuum Steam and EO	Advanced Sterilization Products (ASP) STERRAD® 100S	Advanced Sterilization Products (ASP) STERRAD® NX and 100NX	STERIS Amsco® V-PRO®
CH100	Very light weight package (for example: towel packs or batteries)	3 lbs	3 lbs	10.7 lbs	3 lbs
CH200	Light weight package (for example: telescope with light cord)	6 lbs	6 lbs	10.7 lbs	6.5 lbs
CH300	Light to moderate weight package (for example: general use medical instruments)	9 lbs	9.7 lbs	10.7 lbs	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs	9.7 lbs	10.7 lbs	9.1 lbs
CH500	Heavy weight package (for example: general use medical instruments)	17 lbs	9.7 lbs	10.7 lbs	9.1 lbs
CH600	Very heavy weight package (for example: general use medical instruments)	25 lbs	9.7 lbs	10.7 lbs	9.1 lbs

The following loads were used in the pre-vacuum steam Sterility Validation Studies:

- **CH100**: 16 huck towels (17 in. x 29 in.).
- **CH200**: 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.).
- **CH300**: 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
- **CH400**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 8 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH500**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH600**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the EO Sterility Validation Studies:
• **CH100**: 16 huck towels (17 in. x 29 in.).
• **CH200**: 2 huck towels (17 in. x 29 in.), 2 fluid-resistant drapes (108 in. x 88 in.), 2.5 lbs of metal mass.
• **CH300**: 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
• **CH400**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 7.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH500**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 11.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
• **CH600**: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 100S Sterility Validation Studies:
• **CH100**: Metal Instruments
• **CH200 – CH600**: 15 in. x 10 in. x 1.2 in. tray containing metal instruments.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX Sterility Validation Studies:
• **CH100 – CH600**: 23 in. x 11 in. x 4 in. tray containing metal instruments.

The following loads were used in the STERIS Amsco® V-PR® sterility Validation Study:
• **CH100:** Metal Instruments
• **CH200 – CH600:** 17 in. x 10 in. x 3.5 in. tray containing metal instruments

Note: The loads used in the Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 3.

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.
[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the DuraBlue™ Sterilization Wraps.

Substantial Equivalence

The proposed DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate devices. Both devices:

- Have the same intended use
- Have the same material composition
- Have the same physical and chemical properties
- Have the same configurations/dimensions
- Demonstrate maintenance of package sterility
- Are indicated for the same sterilization parameters
- Are indicated for the same Maximum Wrapped Package Content Weights
- Demonstrate maintenance of package sterility within the period of time for which performance data demonstrating maintenance of sterility has been provided

Table 4: Overall Comparison to Predicate Devices

Element of Comparison	PREDICATE DuraBlue™ Sterilization Wrap (K123857, K123289, and K120658)	PROPOSED DuraBlue™ Sterilization Wrap	Comparison to Predicate

Intended Use	**K123857**: Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using the following modalities:
	• Johnson & Johnson STERRAD 100NX system, Standard, Flex, Express, and DUO Cycles.
	• Johnson & Johnson STERRAD NX system, Standard, and Advanced Cycles.
	The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time aging testing for a duration of 180 days for each indicated modality.
	
	All models of DuraBlue™ Sterilization Wrap have been validated for use with the following Johnson & Johnson STERRAD® 100NX and STERRAD® NX cycles in Table 1 and 2.
	
	Johnson & Johnson STERRAD® 100NX Standard cycle (Max Chamber Load 21.4 lbs)
	• Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load:
	  • an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens
	  • an inside diameter of 1 mm or larger and a length of 1000 mm or shorter of single-channel Teflon®/Polyethylene lumens
	
	Johnson & Johnson STERRAD® 100NX Flex cycle (Max Chamber Load 21.4 lbs)
	• One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain:
		DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using:
		• Pre-vacuum steam at 270°F/132°C for 4 minutes
		• 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
		• Advanced Sterilization Products (ASP) STERRAD® 100S System
		• Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles
		• Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles
		• Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco® V-PRO™1, Amsco® V-PRO™1 Plus and Amsco® V-PRO™MAX Low Temperature Sterilization Systems
		
		The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.
		
		For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200 and 30 minutes for Models CH300, CH400, CH500, and CH600. Models CH400, CH500, and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.
		
		For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55°C. Models CH400, CH500, and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less.
		
		All models of DuraBlue™ Sterilization Wrap have been validated for Advanced Sterilization Products (ASP) STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.
			Substantially Equivalent

	○ a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter **Johnson & Johnson STERRAD® 100NX Express cycle** (Max Chamber Load 10.7 lbs) • Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens, including *da Vinci*® 3-D scopes **Johnson & Johnson STERRAD® 100NX DUO cycle** (Max Chamber Load 13.2 lbs) • One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: ○ a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter **Johnson & Johnson STERRAD® NX Standard cycle** (Max Chamber Load 10.7 lbs) • Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: ○ an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens ○ an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens **Johnson & Johnson STERRAD® NX Advanced cycle** (Max Chamber Load 10.7 lbs)	All models of DuraBlue™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX cycles in Table 1. **ASP STERRAD® 100NX Standard cycle** (Max Chamber Load 21.4 lbs) • Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: ○ an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens ○ an inside diameter of 1 mm or larger and a length of 1000 mm or shorter of single-channel Teflon®/Polyethylene lumens **ASP STERRAD® 100NX Flex cycle** (Max Chamber Load 21.4 lbs) • One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: ○ a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter **ASP STERRAD® 100NX Express cycle** (Max Chamber Load 10.7 lbs) • Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens, including *da Vinci*® 3-D scopes **ASP STERRAD® 100NX DUO cycle** (Max Chamber Load 13.2 lbs) • One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: ○ a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter	

	• Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: o an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR • One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter	**ASP STERRAD® NX Standard cycle** (Max Chamber Load 10.7 lbs) • Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: o an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens o an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens **ASP STERRAD® NX Advanced cycle** (Max Chamber Load 10.7 lbs) • Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: o an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR o One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: o a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter	
	K123289: Cardinal Health DuraBlue™ Sterilization Wrap is intended to allow sterilization of the enclosed medical device that is to be sterilized by a health care provider using the following modalities: • Pre-vacuum steam at 270°F/132°C for 4 minutes • 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes and maintain sterility of the enclosed device(s) for 180 days. The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time aging testing for a duration of 180 days for each indicated modality. For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200 and 30 minutes for Models CH300, CH400, CH500, and CH600. Models CH400, CH500, and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.	All models of DuraBlue™ Sterilization Wrap have been validated for use with the Amsco® V-PRO™cycles in Table 2. The DuraBlue™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed Amsco® V-PRO™sterilization cycles. **Lumen Cycle**: (Max Chamber Load 19.65lbs) • Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: o an inside diameter of 1 mm or larger and a length of 125 mm or shorter o an inside diameter of 2 mm or larger and a length of 250 mm or shorter o an inside diameter of 3 mm or larger and a length of 400 mm or shorter	

	For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55ºC. Models CH400, CH500, and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less. **K120658:** Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider in the following modalities • Pre-vacuum steam at 270°F/132°C for 4 minutes • STERRAD 100S System • Lumen, Non Lumen, and Flexible Cycles in the Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus, and Amsco® V-PRO® MAX Low Temperature Sterilization Systems The Wrap is intended to allow sterilization of the enclosed medical devices(s) and to maintain sterility of the enclosed devices(s). Maintenance of package sterility was validated with real-time testing for the following durations: • 180 days following sterilization by STERRAD 100S and Amsco V-PRO (Lumen, Non Lumen, and Flexible Cycles). • 30 days following sterilization by pre-vacuum steam at 270°F/132°C for 4 minutes For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200 and 30 minutes for Models CH300, CH400, CH500, and CH600. Models CH400, CH500, and CH600 have been validated for pre-vacuum steam sterilization of lumens 3 mm in diameter or larger and 400 mm in length or less. All models have been validated for STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.	**Non Lumen Cycle**: (Max Chamber Load 19.65 lbs) • Non-lumened reusable metal and non-metal medical devices **Flexible Cycle**: (Max Chamber Load 24 lbs) • Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter	

	All models of DuraBlue™ Sterilization Wrap have been validated for use with the following Amsco® V-PRO™cycles: **Lumen Cycle**: (Max Chamber Load 19.65lbs) • Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: o an inside diameter of 1 mm or larger and a length of 125 mm or shorter o an inside diameter of 2 mm or larger and a length of 250 mm or shorter o an inside diameter of 3 mm or larger and a length of 400 mm or shorter **Non Lumen Cycle**: (Max Chamber Load 19.65 lbs) • Non-lumened reusable metal and non-metal medical devices **Flexible Cycle**: (Max Chamber Load 24 lbs) • Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter		

Element of Comparison	PREDICATE DuraBlue™ Sterilization Wrap (K123857, K123289, and K120658)	PROPOSED DuraBlue™ Sterilization Wrap	Comparison to Predicate
Material Composition	Polypropylene fabric using SMS (spunbond-meltblown-spunbond) production process	Same	Substantially Equivalent
Sterilization Parameters	Pre-vacuum steam at 270°F/132°C for 4 minutes 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°Cand 40%-80% relative humidity for 60 minutes Advanced Sterilization Products (ASP) STERRAD® 100S System Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles Amsco® V-PRO®: Lumen, Non Lumen, and Flexible Cycles in the Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus and Amsco® V-PRO® MAX Low Temperature Sterilization Systems	Same	Substantially Equivalent
Configurations/ Dimensions	Six basis weights Fourteen sizes	Same	Substantially Equivalent
Maximum Wrapped Package Content Weights	Pre-vacuum Steam: 3 to 25 pounds EO: 3 to 25 pounds STERRAD® 100S: 3 to 9.7 pounds STERRAD® NX: 10.7 pounds STERRAD® 100NX: 10.7 pounds Amsco® V-PRO®: 3 to 9.1 pounds	Same	Substantially Equivalent
Sterilization Performance	Pass	Same	Substantially Equivalent
Physical Performance	Pass	Same	Substantially Equivalent
Biocompatibility	Non-cytotoxic, Non-sensitizing, Non-irritating	Same	Substantially Equivalent

Summary of Testing

DuraBlue™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance Document Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002) in this submission and the predicate Premarket Notifications. Testing included sterilization efficacy for the modification of the stainless steel lumen claims for the Amsco® V-PRO® Lumen Cycle, and event related maintenance of package sterility for each indicated sterilization process. Data from testing demonstrates that the DuraBlue™ Sterilization Wrap maintains sterility of the enclosed contents for 365 days following sterilization by pre-vacuum steam, EO, or Amsco® V-PRO™ (Lumen, Non Lumen, and Flexible Cycles), and STERRAD® 100S, STERRAD® NX (Standard and Advanced cycle), and STERRAD® 100NX (Standard, Flex, Express, and DUO cycles). Additionally, the DuraBlue™ Sterilization Wrap has been validated for use with the modified lumen sterilization claims when used with the Amsco® V-PRO® Lumen cycle.

Table 5: Performance Testing of Proposed DuraBlue™ Sterilization Wrap sterilized by Pre-vacuum steam, EO, AMSCO® V-PRO®, STERRAD® 100S, STERRAD® 100NX, STERRAD® NX system

Performance Properties		**Results**
Sterilization Efficacy		PASS
Microbial Barrier Properties	Aerosol Challenge	PASS
	Event Related Shelf Life	PASS- 365 days
Material Compatibility with Indicated Sterilization Method		Compatible
Biocompatibility		Non-irritating

Conclusions:

Based on the results of the biocompatibility and physical performance testing, DuraBlue™ Sterilization Wrap is safe for its intended use. The DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate device, in terms of general intended use, physical performance testing, material composition, sterilization process and compatibility, configurations/dimensions, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Cardinal Health 200, LLC
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1430 Waukegan Road
WAUKEGAN IL 60085

Re: K132060
Trade/Device Name: DuraBlue™ Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 19, 2013
Received: November 20, 2013

Dear Ms. Ford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

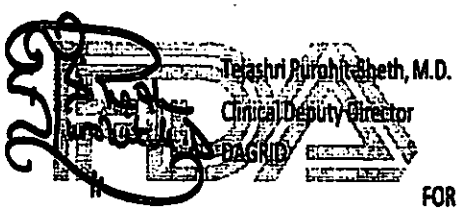
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132060

Device Name
DuraBlue™ Sterilization Wrap

Indications for Use *(Describe)*

DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S system.
- Advanced Sterilization Products (ASP) STERRAD® NX system, Standard and Advanced Cycles
- Advanced Sterilization Products (ASP) STERRAD® 100NX system, Standard, Flex, Express, and DUO Cycles
- Lumen, Non Lumen, and Flexible Cycles in the Amsco® V-PRO® 1, Amsco® V-PRO® 1 Plus and Amsco® V-PRO® maX Low Temperature Sterilization Systems

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.

For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600. Models CH400, CH500 and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.

For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55 °C. Models CH400, CH500 and CH600 have been validated for EO sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less.

All models of DuraBlue™ Sterilization Wrap have been validated for Advanced Sterilization Products (ASP) STERRAD® 100S sterilization of lumens 2.5 mm in diameter or larger and 250 mm in length or less.

All models of DuraBlue™ Sterilization Wrap have been validated for use with the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX cycles in Table 1.

All models of DuraBlue™ Sterilization Wrap have been validated for use with the STERIS Amsco® V-PRO® cycles in Table 2. The DuraBlue™ Sterilization Wrap was validated to be effectively aerated during the pre-programmed STERIS Amsco® V-PRO® sterilization cycles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Mary S. Runner -S
2013.12.13
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Table 1: Validated Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX Cycles

Advanced Sterilization Products (ASP) STERRAD® System and Cycle	Maximum Recommended Chamber Load	Intended Load
ASP STERRAD® NX Standard Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens • an inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens
ASP STERRAD® NX Advanced Cycle	10.7 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens OR One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter
ASP STERRAD® 100NX Standard Cycle	21.4 lbs	Reusable metal and non-metal medical devices, including up to 10 lumens of the following lumen dimensions per chamber load: • an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens (A maximum of five lumens per tray per sterilization cycle)
ASP STERRAD® 100NX Flex Cycle	12.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (A maximum of two flexible endoscopes, one per tray per sterilization cycle)
ASP STERRAD® 100NX Express Cycle	10.7 lbs	Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens
ASP STERRAD® 100NX Duo Cycle	13.2 lbs	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • a single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

Table 2: Validated STERIS Amsco® V-PRO® Cycles

Amsco® V-PRO™ Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.85 lbs	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.85 lbs	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscope(s) may contain either: • a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • two lumens, with one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Table 3: Wrap Model Recommendations[1]

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]			
		Pre-Vacuum and EO	Advanced Sterilization Products (ASP) STERRAD® 100S	Advanced Sterilization Products (ASP) STERRAD® NX and 100NX	STERIS Amsco® V-PRO®
CH100	Very light weight package (for example: towel packs or batteries).	3 lbs	3 lbs	10.7 lbs	3 lbs
CH200	Light weight package (for example: telescope with light cord).	6 lbs	6 lbs	10.7 lbs	6.5 lbs
CH300	Light to moderate weight package (for example: general use medical instruments).	9 lbs	9.7 lbs	10.7 lbs	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments).	13 lbs	9.7 lbs	10.7 lbs	9.1 lbs
CH500	Heavy weight package (for example: general use medical instruments).	17 lbs	9.7 lbs	10.7 lbs	9.1 lbs
CH600	Very heavy weight package (for example: general use medical instruments).	25 lbs	9.7 lbs	10.7 lbs	9.1 lbs

The following loads were used in the pre-vacuum steam Sterility Validation Studies:
- **CH100:** 16 huck towels (17 in. x 29 in.).
- **CH200:** 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.).
- **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (80 in. x 60 in.), 5 lbs of metal mass.
- **CH400:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 8 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH500:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the EO Sterility Validation Studies:
- **CH100:** 16 huck towels (17 in. x 29 in.).
- **CH200:** 2 huck towels (17 in. x 29 in.), 2 fluid-resistant drapes (108 in. x 88 in.), 2.5 lbs of metal mass.
- **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (80 in. x 60 in.), 5 lbs of metal mass.
- **CH400:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 7.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH500:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 11.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm ID x 400 mm) and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® 100S Sterility Validation Studies:
- **CH100:** Metal instruments.
- **CH200 - CH600:** 15 in. x 10 in. x 1.2 in. tray containing metal instruments.

The following loads were used in the Advanced Sterilization Products (ASP) STERRAD® NX and STERRAD® 100NX Sterility Validation Studies:
- **CH100 - CH600:** 23 in. x 11 in. x 4 in. tray containing metal instruments.

The following loads were used in the STERIS Amsco® V-PRO® Sterility Validation Studies:
- **CH100:** Metal instruments.
- **CH200 - CH600:** 17 in. x 10 in. x 3.5 in. tray containing metal instruments.

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 3.

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight and size of individual content types that were validated for the DuraBlue™ Sterilization Wraps.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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